REMARKS

I. Introduction

In response to the Advisory Action dated January 25, 2007, claim 107 has been added. Claims 1, 2, 4, 5, 9-25, 27, 30-37, 39, 43-59, 62, 64-68 and 107 remain in the application. Re-examination and re-consideration of the application, as amended, is requested.

II. Information Disclosure Statement

The outstanding request for continued examination under 37 C.F.R. §1.114 is filed with an Information Disclosure Statement.

III. Claim Amendments

Applicants' attorney has added new claim 107 as indicated above. This claim is fully supported by the specification as filed and introduce no new matter. Support for the interface adapted to attach the apparatus to a user so that the apparatus is carried by the user, wherein the interface comprises a clip, a strap, a clamp, a tape or the like can be found for example in paragraphs [0004], [0009], [0029] and FIG. 1A.

IV. Prior Art Rejections

Pending claims were rejected in view of the disclosure in Dugmore, WO 00/56384. Applicants respectfully traverse these rejections in view of Dugmore in view of the claims presented in the amendment under 37 C.F.R. §1.111 that was filed on August 22, 2006.

The Patent Office states that the Applicants' arguments presented with the amendments to the claims made in the response filed August 22, 2006 that traversed the rejection in view of Dugmore have been fully considered but were not persuasive. Applicants respectfully request a reconsideration of these previously amended claims in view of the further arguments presented below, particularly those relating to the interface element.

A review of the Dugmore reference and the invention recited in the amended claims as well as the reasons for traversing the various rejections under 35 U.S.C. §102(b) and 35 U.S.C. §103(a) are provided below.

1. THE DUGMORE REFERENCE AND THE SUBJECT INVENTION

The Dugmore Reference

Dugmore, WO 00/56384 teaches an adjustable and retractable needle assembly designed to withdraw blood from a patient. The invention disclosed in Dugmore is constructed to protect phlebotomists from needle sticks by having an adjustable needle assembly comprising a needle housing, a first needle guide passage defined in a front end of the housing, a needle that is axially slidable within the passage, and needle length adjusting means, wherein the guide passage defines a central guide axis, and the needle length adjusting means is arranged to deviate the needle laterally relative to the guide axis to adjust the distance that the needle projects from the housing.

As described for example in the first full paragraph bridging pages 8 and 9 and shown in Figures 1-12, this apparatus for withdrawing blood from an individual includes a fluid conduit in the form of a needle having a first sharp front end that functions to pierce the skin of the individual to withdraw blood from a vein. As also described first full paragraph bridging pages 8 and 9 and shown in Figures 1-12, this fluid conduit in the form of a needle further includes a second sharp back end that functions to pierce the stopper of a vacuum phial. When the phlebotomist uses the first end of the needle to pierce the skin and the second end of the needle to pierce the phial stopper, the resulting direct communication with the vacuum chamber defined within the phial results in blood being drawn from the vein into the phial via the needle.

Invention Recited in the Amended Claims

The claims presented in the amendment under 37 C.F.R. §1.111 that was filed on August 22, 2006 focus on those embodiments of the invention used dispense a conduit having an end with structural attributes that allow it to connect to an infusion device. In particular, all independent claims recite constellation of elements that includes (1) a flexible conduit having an end adapted to connect to an infusion device and deliver a fluid from the infusion device through the flexible conduit to an individual having the physiological condition; and (2) an interface for mounting the flexible conduit housing so that it can be carried by a user.

2. APPLICANTS' RESPONSE TO THE REJECTIONS UNDER 35 U.S.C. 102(b)

On page (2) of the Office Action, claims 1-5, 13-14, 17-20, 22-27, 31-39, 43-45, 47-48, 51-54, 56-59, and 64-68 were rejected under 35 U.S.C. §102(b) as being anticipated by Dugmore, WO 00/56384 (Dugmore).

At page 6 of the instant Office Action, the Patent Office stated that the Applicants' previous amendments to the claims and associated arguments relating to Dugmore were not persuasive. Applicants respectfully ask the Patent Office to reconsider the applicability of the Dugmore disclosure in view of the following arguments.

All pending claims now recite "a flexible conduit having an end adapted to connect to an infusion device and deliver a fluid from the infusion device through the flexible conduit to an individual having the physiological condition" This functional limitation was added in accordance with the principles articulated in M.P.E.P. § 2173.05(g) which states "[a] functional limitation is an attempt to define something by what it does, rather than by what it is" and further that such functional limitations "must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used". The text in M.P.E.P. § 2173.05(g) further notes that courts hold that these functional limitations do in fact serve to define the structural attributes of an element, namely those structural attributes that allow the element to function in the recited context. For example, courts hold that "members adapted to be positioned" and "portions . . . being resiliently dilatable whereby said housing may be slidably positioned" serve to precisely define present structural attributes of interrelated component parts of the claimed assembly. *In re Venezia*, 530 F.2d 956, 189 USPQ 149 (CCPA 1976) (emphasis added).

As noted above, Applicants' previous amendments to the claims limited this subject matter to a flexible conduit having an end adapted to connect to an infusion device and deliver a fluid to an individual. In doing so, this functional limitation informs the skilled artisan that the fluid conduit elements recited in these claims are limited to those with conduit ends having the subset of structural attributes that allows them to connect to an infusion device and deliver a fluid from the infusion device to an individual. In this context, the skilled artisan is well aware of the precise structural attributes of an end of a flexible conduit that allows it to connect to an infusion device in this manner. For example, embodiments of fluid conduit ends having typical structural attributes known in the art to allow them to connect to an infusion device are described in U.S. Patent No.

5,097,122 (see, e.g. column 3, lines 43-47), the disclosure of which is incorporated by reference in paragraph [0003] of Applicants' specification.

In view of what is known in the art of infusion devices, one of skill in the art would not agree with the Patent Office's assertion that the sharp needle structures that form the ends of the conduits in the Dugmore reference are capable of performing the intended use of the subject matter recited in Applicants' claims. One of skill in the art would instead note that the needle ends disclosed in Dugmore are specifically designed to easily slip out of any matrix to which they are very temporarily inserted and are therefore unsuitable for use as connector elements in infusion devices. These elements in Dugmore therefore lack the structural attributes that allow them to function as the element as recited in Applicants' claims. In addition, one of skill in the art would further note that once a needle slips out of a matrix, it becomes a unsafe sharp that is know to cause needle-stick injuries, a characteristic explicitly noted in the second and third full paragraphs on page 14 of Dugmore. For this additional reason, the skilled artisan would never consider using a needle end as disclosed in Dugmore to function as a fluid conduit "end adapted to connect to an infusion device and deliver a fluid from the infusion device through the flexible conduit to an individual having the physiological condition" (e.g. as recited in claim 1).

In addition, **the claims further recite an interface element that is not taught of suggested by the Dugmore reference**. For example, claim 107 recites "an interface adapted to attach the apparatus to a user so that the apparatus is carried by the user, wherein the interface comprises a clip, a strap, a clamp, a tape or the like". In view of the method and purpose of operation of the Dugmore apparatus, one of skill in the art would not agree with the Patent Office's assertion that the Dugmore reference teaches this element. In addition, in view of the method and purpose of operation of the Dugmore apparatus, one of skill in the art would have no motivation to modify the Dugmore apparatus to further include this interface element so that the apparatus is carried by the user.

In summary, in accordance with M.P.E.P. § 2173.05(g), the amendments made to the claims relating to the conduit ends serve to precisely define present structural attributes of the recited elements in manner that clearly excludes the needle ends disclosed Dugmore. Because the device disclosed in Dugmore is designed for a completely different purpose and because needle conduit

ends would be both unsuitable and unsafe for use with the claimed invention, one of skill in the art would not agree that Dugmore teaches or suggests this element of the claimed invention.

As noted in M.P.E.P. 2131, to anticipate a claim, a reference must teach every element of a claim. In particular, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single art reference. Because the Dugmore disclosure fails to teach or suggest a fluid conduit having an end adapted to connect to an infusion device, this disclosure cannot anticipate the claimed invention. For this reason, Applicants respectfully request a withdrawal of the rejection under 35 U.S.C. §102(b).

3. APPLICANTS' RESPONSE TO THE REJECTIONS UNDER 35 U.S.C. 103(a)

As noted above, because the device disclosed in Dugmore is designed to perform a completely different procedure that the claimed invention, this reference fails to teach or suggest a fluid conduit having an end adapted to connect to an infusion device. Consequently, this disclosure cannot be combined other disclosures in a manner that renders the claimed invention obvious. Moreover, a detailed analysis of the Dugmore disclosure shows that any modification to the Dugmore apparatus that would lead to the claimed invention (i.e. a modification where sharp second end of the needle is removed and replaced with an end adapted to connect with an infusion device), would not have been obvious because such a modification would in fact compromise the operability of the Dugmore apparatus. In particular, such a modification to Dugmore's pointed second end of the needle conduit would inhibit its ability to pierce the stopper of the blood collection phial. Because Dugmore understandably provides no motivation to modify the invention in a manner that would compromise its operability and/or adapt it to be carried by a user, this reference cannot be used to render the claimed invention obvious.

In order to establish *prima facie* obviousness of a claimed invention, all the limitations must be taught or suggested by the prior art. M.P.E.P. 2143.03, *In re Royka*, 490F.2d 981 (CCPA 1974). Moreover, as noted in M.P.E.P. 2141.02 and 2145, a proposed modification cannot render the prior art unsatisfactory for its intended purpose or change the principle of operation of a reference. Because a modification to the Dugmore apparatus that would result in the invention recited in the pending claims would compromise the operability of the Dugmore apparatus, thereby rendering it unsatisfactory for its intended purpose, the skilled artisan could not have been motivated to make

such a modification. For this reason, the disclosure in Dugmore, ether alone or in combination with other references, cannot be used cannot be used to render the claimed invention obvious.

Applicants' response to the specific rejections articulated in the outstanding Office Action are provided below.

On page (3) of the Office Action, claims 9-11, 15, 43-45 and 49 were rejected under 35 U.S.C. §103(a) as being unpatentable over Dugmore in view of Peterson et al., U.S. Patent Application No. 2003/0098067 (Peterson).

Applicants respectfully traverse this rejection because the disclosure in Peterson fails to remedy the deficiencies of the Dugmore disclosure. In particular, Peterson teaches a tubing reel that includes a replaceable/removable spool (Figures 2-3, [0001]). Peterson provides no disclosure relating to any type of infusion devices or associated components, much less a flexible conduit having an end adapted to connect to an infusion device and deliver a fluid from the infusion device through the flexible conduit to an individual having the physiological condition. For this reason, the Dugmore and Peterson disclosures cannot be combined to produce the claimed invention. Consequently, the claimed invention would not have been obvious in view of a combination of Dugmore and Peterson. Because the Dugmore and Peterson disclosures cannot be combined in a manner that produces the claimed invention, Applicants respectfully request a withdrawal of the rejections to claims 9-11, 15, 43-45 and 49 under 35 U.S.C. §103(a).

On page (4) of the Office Action, claims 12, 16, 21, 46, 50, 55 and 64 were rejected under 35 U.S.C. §103(a) as being unpatentable over Dugmore in view of Novosel et al., U.S. Patent No. 5,975,120 (Novosel).

Applicants respectfully traverse this rejection because the disclosure in Novosel fails to remedy the deficiencies of the Dugmore disclosure. In particular, Novosel teaches a tubing reel that comprises a reel with a tubing hub that allows for the tubing to be withdrawn from both ends to extend and retract the tubing into the clamshell shaped housing (Figures 1-2). Novosel provides no disclosure relating to any type of infusion devices or associated components, much less a flexible conduit having an end adapted to connect to an infusion device and deliver a fluid from the infusion device through the flexible conduit to an individual having the physiological condition. For this

reason, the Dugmore and Novosel disclosures cannot be combined to produce the claimed invention. Consequently, the claimed invention would not have been obvious in view of a combination of Dugmore and Novosel. Because the Dugmore and Novosel disclosures cannot be combined in a manner that produces the claimed invention, Applicants respectfully request a withdrawal of the rejections to claims 12, 16, 21, 46, 50, 55 and 64 under 35 U.S.C. §103(a).

Finally, the various elements of Applicants' claimed invention together provide operational advantages over Dugmore, Peterson and Novosel. In addition, Applicants' invention solves problems not recognized by Dugmore, Peterson and Novosel.

Thus, Applicants submit that independent claims 1, 24, 35, 58 and 107 are allowable over Dugmore, Peterson and Novosel. Further, dependent claims 2-23, 25-34, 36-57 and 59-68 are submitted to be allowable over Dugmore, Peterson and Novosel in the same manner, because they are dependent on independent claims 1, 24, 35, and 58, respectively, and thus contain all the limitations of the independent claims. In addition, dependent claims 2-23, 25-34, 36-57, and 59-68 recite additional novel elements not shown by Dugmore, Peterson and Novosel.

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V. Conclusion

In view of the above, it is submitted that this application is now in good order for allowance and such allowance is respectfully solicited. Should the Examiner believe minor matters still remain that can be resolved in a telephone interview, the Examiner is urged to call Applicants' undersigned attorney.

Respectfully submitted,

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